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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,532	01/30/2004	Robert G. Whirley	021630-004500US	8638

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EXAMINER	
SWEET, THOMAS	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,532	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Thomas J. Sweet	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/20/05

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) 22-35 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 January 2005 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/22/05,9/7/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1, Species A(Figs. 3A-3C), claims 1-21 in the reply filed on 06/20/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The information disclosure statement filed 9/7/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference 64113273 has been withdrawn. It has been placed in the application file, but the reference 64113273 referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities: at the bottom of page 8 is a blank which needs to be filled in.

Appropriate correction is required.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because informal drawing were submitted with the case. Applicant is advised

to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings well be required if allowed and prior to issuance to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 16, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kocur et al (US PGpub 2002/0103527). Kocur et al discloses a graft (fig. 1A) comprising: a graft body 10 section having a proximal end, a distal end, and defining at least one inflatable porous channel 15; a connector member affixed to the proximal or distal end of the graft body

section (abstract), the connector member comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements (abstract),and an inflation medium including at least one therapeutic agent (abstract) configured to be introduced into the inflatable channel.

With respect to claim 4, the porous channel has varying levels of porosity ([0062]).

With respect to claims 5 and 6, the graft body section comprises expanded

polytetrafluoroethylene ([0054]).

With respect to claim 9, the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent (several are listed [0037]-[0051]).

With respect to claim 16, the inflation medium comprises a liquid ([0052]).

With respect to claim 19, the channel comprises one or more features selected from the group consisting of helical spirals, longitudinal channels, and circumferential rings (figs. 1-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kocur et al. Kocur et al discloses a graft as discussed above including one of the objects of the Kocur et al reference is to tune release quantities and times (the full disclosure), there fore it would be inherent and would be fully capable of releasing agent into the body lumen ranges from about 10 micrograms to about 100 milligrams and transport into the body lumen in a time period ranging from about seven days to about twelve months.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Calcote (US PGpub 2002/0091440). Kocur et al discloses a graft as discussed above. However, Kocur et al remains silent as to a channel configuration such as at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel. Calcote discloses another graft including a channel configuration such as at least one inflatable porous cuff disposed at the proximal 48 and distal end 46 of the graft body section and in fluid communication with the at least one channel 44 for the purpose of distributing drug to the graft ([0027]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the channels of Kocur et al in the configuration of at least one inflatable porous cuff disposed at the proximal and distal end of the graft body section and in fluid communication with the at least one channel as taught by Calcote in order to distributing drug to the graft. Such a modification amounts to mere substitution of one functionally equivalent drug distribution system for another within the art of grafts.

Claims 10, 12-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Rhee et al (US 6051648). Kocur et al discloses a graft as discussed above. However, Kocur et al remains silent as to the use of a host polymer for containing the bioactive materials. It is well known in the art of stents to use a host polymer to contain bioactive materials for the purpose of sustained release over time. Rhee et al demonstrates the use of host polymer (polyethylene

glycol) for containing bioactive material(s) in conjunction with a graft (col 18, line 21). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyethylene glycol as a bioactive delivery material in the graft of Kocur et al in order to sustained release over time. Such a modification amounts to mere substitution of one functionally equivalent bioactive delivery material for another within the art of grafts.

With respect to claim 13, the graft body section would inherently and would be fully capable of inhibiting transport of a bulk of the host polymer, since it is the same material disclosed by the applicant.

With respect to claim 14, the host polymer is fully capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation, since it is initially a liquid which is injectable.

With respect to claims 17 and 18, polyethylene glycol is a curable liquid which would inherently and would be fully capable of a cure time ranging from about three minutes to about twenty minutes and a post-cure elastic modulus ranging from about 50 psi to about 400 psi, since it is the same material disclosed by the applicant.

Claims 10-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kocur et al in view of Pacetti et al (US 6663662). Kocur et al discloses a graft as discussed above. However, Kocur et al remains silent as to the use of a host polymer for containing the bioactive materials. It is well known in the art of stents to use a host polymer to contain bioactive materials for the purpose of sustained release over time. Pacetti et al demonstrates the use of host polymer (polyethylene-co-vinyl alcohol, in the

summary of the invention) for containing bioactive material(s) in conjunction with a graft (abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize polyethylene-co-vinyl alcohol as taught by Pacetti as a bioactive delivery material in the graft of Kocur et al in order to sustained release over time. Such a modification amounts to mere substitution of one functionally equivalent bioactive delivery material for another within the art of grafts.

With respect to claim 13, the graft body section would inherently and would be fully capable of inhibiting transport of a bulk of the host polymer, since it is the same material disclosed by the applicant.

With respect to claim 14, the host polymer is fully capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kocur et al. (US PGpub 2004/0030218) and Banik et al. (US PGpub 2003/0120339).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tjs

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E Pellegrino